

Olive Fruit Dry Extract Standardized in Hydroxytyrosol Discussion Paper

Committee Paper for Discussion - ACNFP/163/04

Advisory Committee for Novel Foods and Processes

Application for authorisation as a Novel Food for Olive Fruit Dry Extract Standardized in Hydroxytyrosol. Draft Committee advice for review

Application Number - RP1074

Issue

The Committee completed their assessment of this novel food at the September 2023 meeting further to which a Committee Advice Document was requested to be developed. While developing the document there were some areas where the rationale behind the conclusion was not fully developed and as such the views of the Committee are sought to ensure the outcome of the review is accurately recorded. The Committee is invited to consider the questions detailed below and the early draft Committee Advice Document for this novel food based on the review of the application to date.

Background

1. In April 2021, the FSA received the submission for olive fruit dry extract standardized in hydroxytyrosol, a food supplement ingredient. The novel food ingredient is an extract of *Olea europaea* L. fruit, standardized to either 10% or 20% hydroxytyrosol. The applicant intends to use the novel food as an ingredient in food supplements for those over 18 years of age, excluding pregnant and breastfeeding women.

2. The applicant explains the novel food status has been determined by the Spanish authorities following a consultation process. As such it would be considered not to have a history of consumption in the UK and EU.
3. The focus of the data present has been primarily on hydroxytyrosol on the basis that pure hydroxytyrosol is authorised in dietary supplements in France and Italy, and hydroxytyrosol obtained by chemical synthesis has been authorised in fish and vegetable oils in the EU and UK.
4. The Committee formally requested that the ACNFP Secretariat draft a Committee Advice Document for this novel food. This has been developed and comments are sought on the early draft found in Annex A.
5. It was noted in compiling the Committee Advice Document that some queries on how data provided by the applicant was interpreted to be considered safe were outstanding. The key areas where Committee input is needed to refine the Committee Advice Document is outlined below.

Composition and specification

6. Queries were raised in a previous request for information on the total level of polyphenols present in the novel food. A response was received on this question, see applicant response in Annex B. Members are asked how the answer informs the safety assessment and whether the level of polyphenols indicates a safety concern and the argumentation to support this conclusion.
7. Following a question in the request for information the applicant has provided further proximate analysis for the novel food. Please can member advise whether there are further conclusions to be drawn from this data in the Committee Advice Document. Members are also asked whether the conclusions should be captured under specification or in the nutrition section.

Genotoxicity

8. The applicant has based their data on genotoxicity on a literature review of data both for hydroxytyrosol and other olive extracts. Members are asked to what extent toxicological read-across from the other studies is possible? Are there some studies that are more relevant for the novel food than others? And how should the weight of evidence be interpreted for the novel food.

Toxicology

9. The applicant has based their approach to this section primarily on read-across to data for hydroxytyrosol and limited data on other olive extracts. Following a request for further information further detail has been provided on the calculation of the safe upper intake level from the data. Members are asked whether there are further explanations on the weight of evidence for the safety of the novel food, that need to be included in the Committee Advice Document to accurately reflect the assessment that has been undertaken.

Committee Action Required

- The Committee is asked to review and comment on the early draft of the Committee Advice Document for this novel food.
- The Committee is asked to consider the areas highlighted so the Committee Advice Document can be updated accordingly.

ACNFP Secretariat

November 2023

Annexes

Annex A - Draft Committee Advice Document

Annex B – Response to request for further information from June 2023